



SEP 15 2009

K092304

P'92

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

ESTEEM ORTHO POLYISOPRENE POWDER-FREE SURGICAL GLOVES

Manufacturer: Cardinal Healthcare 222 LTD.
7/111 Moo 4, Highway 3331 Mabyangporn Pluakdaeng,
Rayong, 21140, Thailand

Regulatory Affairs Contact: Tatyana Bogdan, RAC
Cardinal Health, Inc.
1500 Waukegan Road
McGaw Park, IL 60085

Telephone: 847-578-2325

Date Summary Prepared: June 12, 2009

Product Trade Name: Esteem Ortho Polyisoprene Powder-Free Surgical Gloves

Common Name: Surgeon's Gloves

Classification Name: Surgeon's Gloves

Predicate Devices: 1) Esteem Polyisoprene Powder-Free Surgical Gloves previously cleared under K011721 (product code KGO);
2) Ultrafree Max Sterile Latex Powder-Free Surgical Gloves previously cleared under K010862 (product code KGO).

Device Description: Esteem Ortho Polyisoprene Powder-Free Surgical gloves are formulated using synthetic rubber latex. They are offered powder-free and sterile.

Intended Use: Esteem Ortho Polyisoprene Powder-Free Surgical Gloves are a disposable device made of synthetic rubber that is intended to be worn by operating room personnel to protect a surgical wound from contamination in the environments within hospitals and other healthcare facilities.

Substantial Equivalence: Esteem Ortho Polyisoprene Powder-Free Surgical gloves are substantially equivalent to Esteem Polyisoprene Powder-Free Surgical gloves in regard to intended use, sizes, design and product

features; they both are made of synthetic rubber latex using similar manufacturing process and packaging.

Esteem Ortho Polyisoprene Powder-Free Surgical gloves are also substantially equivalent to Ultrafree Max Sterile Latex Powder-Free Surgical gloves in regard to physical characteristics, design and product features. Both gloves are intended for use as specialty orthopedic surgeon's gloves.

Performance Testing:

Test:

Result:

Primary Skin Irritation

Gloves are non-irritating.

Guinea Pig Maximization

Gloves do not display any potential for sensitization.

Dimensions

Gloves meet requirements of ASTM D3577.

Ultimate Elongation
& Tensile Strength

Gloves meet requirements for rubber surgical gloves per ASTM D3577.

Freedom from Holes

Gloves meet requirements of 21 CFR 800.20 and ASTM D3577.

Powder Residual

Gloves meet powder level requirements for "Powder-Free" designation per ASTM D3577 tested using ASTM standard D6124, Standard test method for residual powder on medical gloves. Results generated values below 2mg of residual powder per glove.

Clinical Data:

No clinical data was required.

Conclusion:

The Esteem Ortho Polyisoprene Powder-Free Surgical Gloves meet the technological characteristics of ASTM D3577 and are substantially equivalent to predicate devices identified in this 510(k) summary.



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 15 2009

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Cardinal Healthcare, Incorporated
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K092304

Trade/Device Name: Esteem Ortho Polyisoprene Powder-Free Surgical Sterile Gloves
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: August 28, 2009
Received: August 31, 2009

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

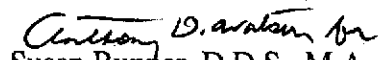
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



Cardinal Health

Indications for Use

510(k) Number (if known): K092304

Device Name: Esteem Ortho Polyisoprene Powder-Free Surgical Sterile Gloves

Indications for Use: These powder-free surgeon's gloves are a disposable device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination in the environments within hospitals and other healthcare facilities.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shela R. Murphy MD
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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